cost and/or insufficient clinical advantage over other therapies. Interviewed EU5 payers, meanwhile, demand robust demonstration of improvement over existing agents for favorable health technology assessment (HTA) of personalized therapies, and increasingly seek cost-sharing schemes. However, most surveyed US and EU5 oncologists preferentially prescribe biomarker-driven agents where appropriate (e.g. 80% of US respondents most frequently use crizotinib first-line for ALK-positive NSCLC), despite prior authorization and reauthorization being commonly required in the US, and country-specific cost-containment measures (e.g. physician budgets in Germany and prescribing monitoring registries in Italy) being key prescribing hurdles in the EU5. **CONCLUSIONS:** Strong, demonstrable advantages over existing agents and pricing compromises are required to secure favorable reimbursement for biomarker-driven treatment. While prescribers favor personalized medicine, payers require proven value for money. Manufacturers must strive to optimize trial design to help convince payers to see beyond the price tag, and be prepared to balance price expectations with uptake potential to optimize market access.

PCN136

CHARACTERIZATION OF TEMOZOLOMIDE UTILIZATION IN GLIOBLASTOMA

Hill K[1], Jiang S[2], Patel D[2], Worthington K[1]
[1]*Celldex Therapeutics, Hampton, NJ, USA,* [2]*Pharmerit International, Bethesda, MD, USA*

OBJECTIVES: To characterize the usage of Temozolomide (TMZ) in a real-world setting among patients with glioblastoma. **METHODS:** Adult patients diagnosed with malignant brain cancer (ICD9-CM, 191.XX), who underwent brain-related surgery 90 days prior to the first TMZ dose and had ≥ 24 months of continuous enrollment, were identified in the IMS Pharmetrics Lifelink Plus claims database. The TMZ + radiation subgroup was used to reflect glioblastoma patients and differentiate them from patients with lower-grade gliomas. Descriptive statistics were generated for patient demographics, insurance-related variables, co-diagnoses, concomitant medications, chemotherapy cycle-duration, and TMZ dose. The index date was defined as the first claim for TMZ, and certain variables were assessed for pre- and post-12 month periods. Statistical comparisons between pre- and post-index were performed using McNemar's tests. **RESULTS:** A total of 1,126 patients met the inclusion criteria and the mean age was 52.7 yrs. (SD=10.9). There was a significant increase in the use of concomitant medications (antianxiety, antidepressants, and antiemetic) as well as co-diagnoses (depression, fatigue, seizure/epilepsy, and hearing loss) in the post-index period ($p<0.001$). However, in this same period, corticosteroid and pain medication use significantly decreased as did the co-diagnoses of aphasia and headache ($p<0.001$). TMZ mean starting dose, duration, and number of maintenance phase cycles was 154.4 mg (SD=77.9), 46 days (SD=12), and 7 cycles (SD=3), respectively. Following the first dose, 73% of patients experienced a TMZ dose increase. **CONCLUSIONS:** Post-index, patients experienced a complex change in both concomitant medications and co-diagnoses, possibly reflecting both a decrease in tumor mass and side effects of the TMZ + radiation therapy. These initial findings warrant further investigation of TMZ as real-world standard-of-care in glioblastoma.

PCN137

METASTATIC MELANOMA PATIENT CHARACTERISTICS AS A DETERMENING FACTOR FOR BRAF GENE MUTATION TESTING AND TREATMENT IN CANADA – A RETROSPECTIVE COHORT STUDY

Djokic S[1], Lapierre M[2]
[1]*IMS Health, Ottawa, ON, Canada,* [2]*IMS Health, Kirkland, QC, Canada*

OBJECTIVES: To characterize patients and treatment approaches relative to BRAF gene mutation testing. **METHODS:** An analysis of patient characteristics, diagnostic and treatment including BRAF testing, age, co-morbidities, number of tumor sites, hospital vocation and type of therapy used was conducted using the information included in the IMS Brogan Enhanced Tumor Study database from October 2013 to September 2014. **RESULTS:** Out of 343 stage IV melanoma patients, 239 were tested for BRAF mutations. 57% (136 pts.) were BRAF positive, 36% (87 pts.) BRAF negative and for 7% (16 pts.) results were not reported. Patients who were tested for BRAF tended to be less than 50 years of age (46% vs. 16%, $p<0.01$), have none or only 1 co-morbidity (87% vs. 70%, $p<0.01$), have only 1 metastasis (34% vs. 45%, $p<0.05$), and treated in an academic facility (74% vs. 50%, $p<0.01$) compared to those who were not tested. BRAF negative patients were more often treated with ipilimumab compared to those who were not tested (42% vs. 10%, $p<0.01$). **CONCLUSIONS:** Patients characteristics emerged as an important factor for determining diagnostic and treatment protocols for metastatic melanoma patients in Canada. Younger patients and those with more favorable disease characteristics are more likely to be tested for BRAF mutations and treated with ipilimumab in those without BRAF mutation. BRAF testing appears to be more prevalent in academic centers than in community hospitals.

PCN138

BURDEN OF SYSTEMIC LIGHT-CHAIN (AL) AMYLOIDOSIS: A SYSTEMATIC LITERATURE REVIEW

Mehta S[1], Cooke C[1], Gao X[1], Labotka R[2], Berg D[2], Parameswaran H[3], Lin HM[2]
[1]*Pharmerit International, Bethesda, MD, USA,* [2]*Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, Cambridge, MA, USA,* [3]*Medical College of Wisconsin, Milwaukee, WI, USA*

OBJECTIVES: To conduct a systematic literature review on relapsed or refractory AL amyloidosis, focusing on clinical outcomes, epidemiology, health-related quality-of-life (HRQoL) and economic aspects. **METHODS:** MEDLINE and EMBASE databases were searched for English-language articles published in the last 10 years using search terms including "Primary/Systemic amyloidosis", "epidemiology/prevalence/incidence", "therapeutics/drug therapy/outcome", "patient-reported/quality-of-life/satisfaction and "economics/cost" etc. Search results were manually reviewed, and relevant studies were selected for inclusion as appropriate. Additional references were obtained from clinical conferences and the reference lists of selected articles. **RESULTS:** 1,141 articles were initially retrieved, and 58 were included in the current review. Given the rare nature of the disease, it was difficult to obtain accurate incidence and prevalence data, but incidence estimates were found to be 5-12 people/million/year in US. AL amyloidosis is associated with early mortality (median survival <3 years in many series) and a 42-64% rate of non-response or progression. Costly complications of AL amyloidosis include disease-related organ failure. For example, kidney involvement is present in about 70% of patients, and rates of dialysis in patients with AL amyloidosis range from 5-18% with mean total 12-month healthcare costs (inpatient, outpatient and indirect costs) for patients receiving dialysis being $99,776. There are no disease specific patient-reported outcome (PROs) tools developed for AL amyloidosis, but patients report severe psychological distress, anxiety and also experience unintentional weight loss. There are no consistent clinical guidelines for treatment of AL amyloidosis especially after relapse as no drug has received FDA or EMA approval for this indication. Overall, limited efficacy and significant toxicity are still major concerns with current therapy. **CONCLUSIONS:** Limited epidemiologic and health outcomes data exist in the literature for relapsed or refractory AL amyloidosis. Treatment options are insufficient. New therapies which offer better clinical outcomes with less toxicity are needed to improve patient care.

PCN139

THE IMPACT OF ENDOSCOPIC LINEAR STAPLING DEVICE STABILITY IN THORACIC SURGERY: A DELPHI PANEL APPROACH

Miller D[1], Gonzalez Rivas D[2], Meyer K[3], Clark RS[4], Kohno T[5]
[1]*WellStar Medical Group, Austell, GA, USA,* [2]*Coruña University Hospital, Coruna, Spain,* [3]*Xcenda Corporation, Tampa, FL, USA,* [4]*Xcenda, Palm Harbor, FL, USA,* [5]*Toranomon Hospital, Tokyo, Japan*

OBJECTIVES: To develop consensus statements outlining the impact of endoscopic linear stapling device stability on potential complications of thoracic surgery and the stress/concern of thoracic surgeons. **METHODS:** An 8-member expert panel of practicing thoracic surgeons representing eight different countries participated in a Delphi panel process that included two anonymous surveys. The first survey included binary, multiple-response, and Likert scale type questions, which were then converted into affirmative statements for the second survey if an adequate number of respondents answered similarly. Consensus was defined a priori when ≥70% of respondents agreed with the affirmative statement in survey 2. **RESULTS:** All 8 panelists (100%) completed surveys 1 and 2. Panelists unanimously agreed an endoscopic linear stapling device with improved stability would result in less stress/concern for critical firings, surgeries where a fellow is being trained, and robot-assisted surgeries requiring an assistant. Across all tissue types, all panelists agreed that reduced unintentional tissue/structure damage and reduced tension on tissue being fired upon may result from use of an endoscopic linear stapling device that provides improvement in stability. The panel unanimously considered endoscopic linear stapling device stability to have more clinical importance in VATS thoracic surgery compared to open thoracic surgery. **CONCLUSIONS:** Improved endoscopic linear stapling device stability is a critical component of thoracic surgery that is likely to result in more frequent positive surgical outcomes when compared to a device with greater instability.

PCN140

THE EXPECTED IMPACT OF ONCOLOGY BIOSIMILARS IN BRAZIL AND MEXICO: PAYERS AND ONCOLOGISTS CONSIDER THE COST-EFFECTIVENESS OF THESE CHEAPER ALTERNATIVES

Zevallos S[1], Ribeiro A[1], Cox J[2]
[1]*Decision Resources Group, Burlington, MA, USA,* [2]*Decision Resources Group, London, UK*

OBJECTIVES: Brazil and Mexico present an attractive opportunity for biosimilar manufacturers. The majority of patients in these key Latin American markets rely entirely on government-sponsored healthcare. These public healthcare systems continually strive to limit any premium costs in favor of increasing their suboptimal coverage, particularly of biologics for oncology. This study explores the expected impact of more cost-effective biosimilar alternatives on coverage and prescribing for key oncology indications in Brazil and Mexico. **METHODS:** Across Brazil and Mexico, 100 medical oncologists and 60 hematologists were surveyed regarding their views on biosimilars for breast cancer, colorectal cancer, and Non-Hodgkin's lymphoma, and on current and expected biologics prescribing patterns. Additionally, 8 payers who influence reimbursement at a national or regional/institutional level were interviewed. **RESULTS:** Up to 41% of biologics-eligible public patients with a given tumor type do not currently receive a biologic, according to surveyed physicians in Brazil and Mexico. Respondents largely attributed low access to limited coverage for oncology biologics. Surveyed physicians and interviewed payers anticipate improved access to biologics upon biosimilar launch and an overall reduced burden from oncology biologics to the healthcare systems. Although surveyed specialists indicate some initial caution regarding the bioequivalence of biosimilars, they nevertheless foresee widespread biosimilar uptake. In Brazil's public sector, for example, respondents expect that 70% of Herceptin-eligible breast cancer patients will receive biosimilar trastuzumab. **CONCLUSIONS:** Oncology biosimilars should find fertile terrain in Brazil and Mexico. Automatic substitution in the public sector is likely, although interchangeability regulations are currently under discussion in both markets. Cost-effectiveness combined with pharmacovigilance and robust long-term safety data will play a major role in the continuous uptake of biosimilars versus brands, with the latter securing reasonable market share only if priced competitively.

PCN141

PROMOTING MARKET ACCESS THROUGH BREAKTHROUGH THERAPY DESIGNATION: CAN THIS ACCOLADE HELP CONVINCE PAYERS AND PRESCRIBERS?

Duval A, Cox J
Decision Resources Group, London, UK

OBJECTIVES: The breakthrough therapy designation (BTD) pathway aims to expedite approval of drugs for serious and life-threatening conditions. BTD has been awarded to numerous oncology agents in development. This study assessed the likely impact of BTD on payer and prescriber perceptions of novel therapies, and its potential to